Spectranetics

K112032
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510(k) Summary

(As Required By 21 CFR 807.92)

This 510(k) Summary of safety and effectiveness for the Spectranetics 8Fr Turbo-Tandem® System is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(k) summary.

Submitter Information

Company name:	Spectranetics Corporation
Company address:	9965 Federal Drive Colorado Springs, CO 80921
Company phone:	(719) 477-2000 (800) 633-0960
Company fax:	(719) 447-2040

Device Identification

Device trade name:	8Fr Turbo-Tandem® System
Device common name:	Percutaneous guide catheter with laser atherectomy catheter
Classification:	Catheter, percutaneous
Device class:	Class II (per 21 CFR 870.1250 and 870.4875)
Device code:	DQY and MCW
Establishment Registration number:	3007284006

Performance Standards

There are no performance standards applicable to this device.

Device Description

The Turbo-Tandem® System (Laser Guide Catheter with Laser Atherectomy Catheter) is a laser atherectomy catheter constrained within a guiding catheter to facilitate the offset (biased position) of the laser atherectomy catheter. Specifically, the guiding catheter portion of the Turbo-Tandem® System includes an angled biasing tip to offset the distal end of the incorporated laser catheter from the central plane of the vessel lumen allowing for circumferential guidance and positioning of the laser catheter within the vessel.

The incorporated laser catheter of Turbo-Tandem® System is constructed of multiple optical fibers arranged circumferentially around a 0.014" (0.35mm) guidewire compatible lumen and has a fiber optic surface area similar to a 2.0mm laser catheter. The laser catheter has a radiopaque marker bands at the distal tip. The laser catheter is connected to the Spectranetics CVX-300® Excimer Laser System by means of an optical coupler and tail-tubing.

The guiding catheter portion of the Turbo-Tandem® System is comprised of a handle with an incorporated flush port, a braided shaft with hydrophilic coating, and a biasing tip with two radiopaque marker bands. The handle features a six-position locking mechanism to position the laser catheter on the ramp of the biasing tip.

The Turbo-Tandem® System is provided sterile and is intended to be single-use.

Indication for Use

The Turbo-Tandem® System is indicated for atherectomy of infrainguinal arteries.

Substantially Equivalent Device

The Spectranetics 7Fr Turbo-Tandem® System (K094036) is the predicate device to the 8Fr Turbo-Tandem System. The 8Fr Turbo-Tandem System is similar to the predicate device with regards to design, the only change being the size of the biasing tip (7Fr to 8Fr). The IFU have been modified to specify instructions for both the 7Fr and 8Fr models.

The intended use, intended patient population, and mode of operation are comparable to the predicate device. The materials of construction, packaging, biocompatibility, sterilization, and shelf-life are identical to the predicate device.

Summary of Studies

Spectranetics performed device integrity testing to support the claim that the 8Fr Turbo-Tandem System is substantially equivalent to the predicate device. All device integrity tests for the Spectranetics 8Fr Turbo-Tandem System met the specified requirements which consisted of:

- Dimensional test
- *In vitro* tip position functional test
- *In vitro* performance test
- Laser ablation performance test
- Physical test
- Accelerated age test

Conclusion

Numerous similarities support a determination of substantial equivalence to the 7Fr Turbo-Tandem. Based on data and information presented, it can be concluded that the 8Fr Turbo-Tandem that the device is as safe, as effective, and performs as well as or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 17 2011

Spectranetics Corporation
c/o Shelley Wilcox
Senior Regulatory Affairs Specialist
9965 Federal Dr.
Colorado Springs, CO 80921

Re: K112032
Trade/Device Name: 8Fr Turbo-Tandem System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, MCW
Dated: July 14, 2011
Received: July 15, 2011

Dear Ms. Wilcox:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. However, we remind you that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ~~TBD~~ K112032

Device Name: 8Fr Turbo-Tandem® System

Indications For Use:

The Turbo-Tandem® System is indicated for atherectomy of infrainguinal arteries.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112032